EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Wave 11 Cases*	

GENERAL PROLIFT PROLIFT+M EXPERT REPORT OF CHARLES R. HANES, II, MD, FACOG, FPMRS

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REGARDING ETHICON'S PROLIFT PRODUCTS

My Background

I attended Vanderbilt University, majored in biology, and earned a BA degree in 1967. I attended medical school at Tulane University in New Orleans and earned an MD degree in 1971. I returned to Vanderbilt and spent two years in the general surgery residency program.

From 1973-1975, my postdoctoral education was interrupted by a military obligation. In 1973, I was stationed in the U.S. Army medical corps as a battalion surgeon with the 1st battalion, 81st field artillery regiment at Wiley Barracks in Neu Ulm, Germany. In 1974, I was transferred to Camp Darby in Tirrenia, Italy where I functioned as a partially trained surgeon in the U.S. Army hospital.

In 1975, I returned to complete my residency training in the specialty of Obstetrics and Gynecology at Emory School of Medicine in Atlanta, Georgia. During this time, I had the good privilege of working under some of the most outstanding vaginal surgeons in the country. Dr. John D. Thompson was the chairman of the department. Dr. Cullen Richardson and Dr. John Ridley were both on the clinical faculty. I operated with all three of these men and learned much of what I know based on that experience. I completed my residency training in 1978 and have been engaged in the private practice of medicine since then. I moved to Mobile, Alabama in 1979 and have been in practice continuously ever since.

For approximately 24 years, I functioned as a generalist in ObGyn. I stopped obstetrics in 2002 and began to focus my gynecologic practice on urogynecology. At the time, there was very little formal training in the subspecialty. I attended numerous meetings and spent times with many of the leaders in the field, attending courses and spending time in their operating suites observing surgery.

In 2006, I left the group that I was affiliated with so that I could limit my practice exclusively to urogynecology and be able to build a referral-based practice with other ObGyn groups in the area.

In 2011, the American Board of Medical Specialties (ABMS) officially recognized Female Medicine and Pelvic Reconstructive Surgery as a subspecialty. In so doing they acknowledged that a specific skill set is needed for the successful treatment of women who have pelvic floor disorders. These fall primarily under the category of incontinence and pelvic organ prolapse (POP). A board certification examination was offered for the first time in 2013. I sat for and passed the board exam in that first year.

In 2017, I relocated my practice to the University of South Alabama health care system. I am a full-time employee of the university. I spend 75% of my time in private practice and 25% teaching medical students and ObGyn residents. One aspect of my teaching responsibility is to train residents on MUS. This involves teaching the indications for surgery, the technique of implantation, and the management of postoperative care and complications. For the most part, these fall into the category of vaginal pain, dyspareunia, mesh erosions, and voiding problems.

In the course of my career, prior to the introduction of synthetic mesh products for the surgical repair of pelvic organ prolapse (POP), I performed over one thousand native tissue repairs. These included anterior colporrhaphy for anterior compartment defects (cystocele), posterior colporrhaphy for posterior defects (rectocele), and both uterosacral ligament suspensions (USLS) and sacrospinous ligament suspensions (SSLS) for apical prolapse. I also performed many obliterative vaginal procedures for advanced POP in elderly patients who were no longer sexually active.

After 2005 and the availability of the mesh products, I became interested in incorporating this modality into my practice. I had already been using the mesh midurethral sling (MUS) products for six years and had become comfortable with the use of synthetic mesh in the arena of vaginal surgery. After observing results of my peers for the first year or two, I became convinced that there were clear advantages offered by the use of these mesh products.

I began using the Gynecare (Ethicon) Prolift products sometime in 2006 and have performed well over 500 POP repairs between 2006 and 2012 when the products were removed from the market. In addition to this, I have accumulated vast experience in treating complications of mesh related complications. This includes revision as well as total removal of the mesh.

In the course of preparing my opinions for this report, I have reviewed medical literature, incorporated my own professional experience. I have also reviewed numerous Ethicon documents to include the Prolift and Prolift +M IFUs, professional education materials and the 2007 Surgeon's Monograph. A list of materials that I may use in future trials is attached to this report. I've also read reports from various Plaintiffs' experts and considered the materials cited therein.

All my opinions are held to a reasonable degree of scientific and medical certainty. In short, I believe that Prolift and Prolift +M were safe and effective, state of the art products for the repair of pelvic organ prolapse. They were not defectively designed. These products provided superior anatomical outcomes compared to native tissue repairs and presented an acceptable risk/benefit profile with complications similar to those of native tissue repairs to include dyspareunia, pain, scarring and anatomical distortion. Ethicon adequately warned of the risks of Prolift and Prolift +M in its IFUs and provided additional materials in its professional education materials and the 2007 Surgeon's Monograph. Regardless, all of the complications associated with the use of Prolift or Prolift +M were basic risks of any vaginal POP repair and were commonly known by pelvic surgeons at the

time Prolift was first sold in 2005. All of my opinions in this report are based upon my ongoing review of the medical literature, my education, training, experience and collaborations with colleagues.

My Testimonial History

I have been deposed as an expert witness on two cases:

Noles v. Ethicon and Aldridge v. Ethicon.

I charge $450.00 per hour for legal consulting and $5000 per day for court appearances.

Pelvic Organ Prolapse

Prolapse occurs in women following damage to the pelvic floor. It is thought that the major risk factor is vaginal delivery. Injuries occur to the muscles and fascial support structures in the pelvic floor that normally support the pelvic organs – rectum, uterus, vagina, and bladder. This may be immediately apparent, but often these injuries are not evident to the woman and may remain asymptomatic for many years. With the passage of time, the constant effects of physical activity, normal weakening associated with aging, and decreasing production of estrogen, the descent of the pelvic floor structures increases and eventually becomes apparent once the leading edge of descent reaches the vaginal opening.

There are other risk factors that lead to prolapse including hysterectomy that can result in weakening of the fascial supports that suspend the upper vagina. Up to 40% of women will develop POP following hysterectomy (Symmonds, 1981, Marchionni, 1999).

Also smoking tobacco has long been recognized as a factor in weakening of connective tissue. Any activity associated with repeated high pressure generation within the abdominal cavity is also contributory such as strenuous physical activity, weight lifting, straining associated with chronic constipation, and chronic coughing secondary to pulmonary disease.

POP is graded according to the level of descent of the most dependent point. If it remains more than one centimeter above the vaginal opening, it is a stage 1. Stage 2 involves further descent down to one centimeter beyond the opening. Stage 3 refers to descent to a point equivalent to 3/4s of the total vaginal length and stage 4 is essentially total eversion. It is unusual for a woman with stage one prolapse to be aware of any symptoms, but as the descent progresses, symptoms increase.

The feeling of pressure is almost universal once the level of descent reaches or advances beyond the vaginal opening. Many women complain of low back pain that is relieved by lying down; however, the only way to substantiate this as a consequence of the prolapse is to determine if it resolves following correction. Vaginal pain and dyspareunia are not common complaints although many women state that sexual activity is impaired.

Additional symptoms depend on the organ affected. With anterior compartment prolapse (cystocele), bladder function is impaired. There may be an obstruction to outflow of urine resulting in difficulty voiding and elevated residual urine volumes that, in turn, may lead to recurrent bladder infections (UTIs). If the tissues underlying the bladder neck and urethra are included in the area of weakness, urinary incontinence becomes a frequent complaint.

When the posterior compartment is affected (rectocele), symptoms may include difficulty having bowel movements. Not infrequently, women will describe the necessity to manually reduce the prolapse in order to accomplish defecation.

In addition to the troubling physical symptoms, there is frequently a profound psychological impact as women often become socially isolated out of fear that urinary incontinence, a frequent accompaniment of prolapse, will occur (Abdel-Fattah, 2011). In addition, the discomfort that may be present with sexual

intercourse may place a strain on her marriage. For all of these reasons, women usually come to a point where they seek definitive treatment.

Approximately 11% of American women will have an operation for incontinence and/or prolapse in their lifetime (Fialkow, 2008). Approximately 220,000 surgeries are performed every year in the United States for the correction of POP (Brown, 2002). 29-40% of these women who have surgical repair will have the prolapse reoccur within three years of surgery (Olsen, 1999).

Nonsurgical POP treatments

Nonsurgical treatment of POP involves either expectant management or the use of a vaginal splint referred to as a pessary. Expectant management consists of no intervention but monitoring for any further progress in the level of descent or bothersome symptoms. In early stage prolapse, studies have shown that the majority will worsen over time, but a significant number do not progress and there are even a small percentage that improve. In younger, active women, progression is expected.

The use of a pessary may provide satisfactory relief of symptoms and is especially helpful in those women who do not want surgery, are at high risk for complications, or who simply want a temporary measure to enable them to delay surgery. Prolonged usage frequently is associated with bothersome side effects such as vaginal discharge and irritation. The large majority of women do not find pessary use to be a satisfactory long-term solution and eventually opt for surgical repair.

Native tissue surgical repair

Reconstructive pelvic surgery to restore normal vaginal anatomy is most frequently performed using the native tissue of the patient. Anatomically, there are layers of endopelvic fascia that envelop the pelvic organs. The objective is to identify the defects within these fascial layers that have occurred due to tearing or stretching. These are then sutured back together. When the defect is between the vagina and

bladder (cystocele), the operation is referred to as an anterior colporrhaphy. A posterior colporrhaphy is performed when there is a fascial defect between the vagina and the rectum (rectocele).

When the fascial and ligamentous supports that suspend the apex of the vagina are disrupted, resuspension is required. The native tissue support structures most frequently used, when the procedure is performed through the vagina, are either the uterosacral ligaments or the sacrospinous ligaments.

Success and complications of native tissue repairs

Several studies have shown that recurrence rates of prolapse after anterior and posterior colporrhaphy are in the order of 30-70%. (Weber, 2001, Lavelle, 2016). USLS and SSLS can succeed in resuspending the vaginal apex, but failure may occur if the native tissues are inherently weak as is often the case in women with POP. In addition to a high failure rate, the SSLS creates a posterior deviation of the vaginal axis that may result in dyspareunia as well as an increased risk of cystocele formation. (Holley, 1995)

Whiteside surmised that native tissue repairs could only restore 50% of the pre-operative strength of the pelvic floor tissues accounting for a recurrent prolapse rate at one year of follow up of 58% (Whiteside, 2004).

Graft augmented repairs

Graft augmentation refers to surgical repairs that use supplemental foreign material to reinforce the native tissues. Grafts come as either biological or synthetic products. Much of what we know about graft usage comes from the collective experience in hernia repair surgery. Biological graft materials and later synthetic grafts became widely used in the 1950s. In 1962, Lane reported on the use of synthetic mesh for abdominal sacral colpopexy (ASC) (Lane,1962). This operation was performed through an abdominal incision and suspended the apex of the vagina to the anterior longitudinal ligament that covers the front surface of the sacrum. By the 1990s, the

use of synthetic mesh to repair prolapse was common and well within the standard of care (Iglesia 1997).

Studies comparing the vaginal suspensions with the abdominal sacral colpopexy soon revealed superior outcome with the abdominal approach. In 1996, a randomized controlled trial compared SSLS native tissue repair with ASC. Surgical success was reported at 29% for SSLS and 58% for ASC. Furthermore reoperations because of failure were required for 33% of the SSLS patients compared with 16% in the ASC group. (Benson, 1996)

A Cochrane review reported on 22 surgical trials involving 2368 women and concluded that ASC was superior to native tissue vaginal repairs with lower recurrence of POP and lower reoperation rates. (Cochrane 2007)

Initially, ASC was performed through an open abdominal incision. Eventually, laparoscopic techniques enabled it to be accomplished with a minimally invasive technique. Later, the incorporation of robot assistance made the laparoscopic technique much easier and, therefore, made the surgery more available to a larger number of gynecologists who were not proficient in difficult laparoscopic procedures. Use of the robot, however, resulted in much longer operating times at a much higher cost per case (Paraiso). Furthermore, all of these abdominal procedures were associated with complications that were not encountered with vaginal surgery including bowel injuries, postoperative ileus, incisional hernias, and wound infections.

Because of high failure rates with native tissue repairs and higher complication rates with the abdominal repairs (not to mention their high rates of morbidity and invasiveness), there was a growing desire to find a way that a durable transvaginal repair could be performed that would address both cystocele and rectocele defects as well as an apical suspension that would provide results comparable with ASC.

History of Prolift

Prior to the introduction of any of the corporate mesh kits that combined the mesh with insertion devices, free mesh began to be used for POP repair. Studies reported on the successful use as well as superior results especially with cystocele repairs that had previously demonstrated such a high failure rate with the native tissue repairs. (Julian 1996, Flood 1998, Hardiman 2000). Using these techniques, the surgeon would cut a sheet of mesh to conform to the proper shape to cover the defect being addressed and suture it to fascial or ligamentous structures to hold it in place until tissue incorporation had time to occur.

Gynemesh PS made from the same Prolene material used in Prolene sutures and Ethicon's TVT had already demonstrated safety and efficacy with the midurethral sling procedures that had been introduced in 1998 for the correction of stress urinary incontinence. In 2002, the FDA cleared Gynemesh PS for use in POP surgery. Gynemesh PS consists of a mesh that is larger pore and lighter weight than that used in the TVT products. It is a type I macroporous polypropylene mesh (which is recognized world-wide for its biocompatibility and ability for excellent tissue integration) with a pore size of approximately 2.4 mm and a weight of approximately 43 grams per meter squared. The larger pore size and lighter weight of Gynemesh PS compared to Prolene mesh is better suited to support the larger anatomical structures inherent in POP repair. Gynemesh PS was (and is) a state of the art device for the treatment of POP.

In 2002, a group of French surgeons developed a transvaginal technique using the Gynemesh PS that they termed transvaginal mesh (TVM). After several years of study by the French group (Debodinance 2004; Cosson 2005), the TVM was introduced in 2005 by Ethicon under the brand name Prolift. When Prolift was launched in 2005, the TVM data demonstrated the safety and efficacy of Prolift. Over 600 patients were evaluated prior to Prolift's launch in which Gynemesh PS was used and similar surgical tools were utilized to that which were contained in

the manufactured Prolift. This large reservoir of clinical data exceeds industry standards for available clinical data prior to the launch of Prolift. Given the long standing safety profile of Prolene mesh reflected in 7 years of data from the TVT products, and the data available on Gynemesh PS—to include that from the TVM group, the 2003 Gynemesh PS White Paper and a one year study presented at AUGS (Lucente 2004)—I believe that adequate and sufficient data existed prior to Prolift's launch to support its safety and efficacy.

Early Results of Prolift

By 2009 more than 30 studies documented a favorable benefit to risk ratio with the Prolift operation using Gynemesh PS. To date over 100 studies have evaluated the safety and efficacy of Prolift making it the most studied device to repair POP in history. Several randomized controlled trials have demonstrated anatomic superiority of Prolift over native tissue repairs as well as statistically significant improvement in quality of life (da Silveira 2015; Sokol, 2012; Withagen 2011; Sokol 2012; Svabik 2014; El Nazer 2012; Halaska 2012; Altman 2012). Similar results have been found in studies comparing native tissue repairs to those utilizing Gynemesh PS (Carey 2009). These results have also been reflected in long term studies (Pecheux 2018; Ubertazzi 2018; Luo 2018; Lo 2017; Kraus 2017; Song 2016; Santos 2016; Svabik 2016; Meyer 2016;Khan 2014; Jacquetin 2013; De Landsheere 2012; Benbouzid 2012; Miller 2011).

The largest study randomized 389 women into two groups, 200 who had an anterior Prolift and 189 who had a native tissue anterior colporrhaphy. The study collected data from 53 hospitals in Scandinavian countries performed by 58 surgeons. Using a stringent definition of cure, the Prolift patients had a lower failure rate (39.2%) compared with native tissue (65.5%). Six (3%) of the Prolift patients required repeat surgery for mesh revision. There was no difference in de novo dyspareunia, pelvic or vaginal pain (Altman, 2011)

All of the studies showed anatomic results that exceeded those of the native tissue

repairs with which they were compared. In addition, patient satisfaction was extremely favorable. quality of life, voiding symptoms (El-Nazer, 2012), bowel symptoms (Withagen, 2011), and sexual function (El-Nazer, 2012) were improved.

In the 2016 Cochrane review comparing transvaginal mesh with native tissue repairs, the mesh operations were found to have better subjective and objective outcomes, and lower reoperation rates (Maher, 2016). This review also found no difference in the rates of de novo dyspareunia and repeat surgery for continence and found that the rates for prolapse re-operation and awareness of prolapse at one to three years was less likely when mesh was utilized. While the overall rate of re-operation was higher in the mesh arm, this is due to the occurrence of mesh exposure, which was found to be around 8%. Oftentimes, mesh exposures are asymptomatic and require no treatment. When symptomatic, a mesh exposure is often treated in a very minor outpatient procedure when the exposed portion of the mesh is excised. Schimpf's 2016 meta-analysis found similar results concluding: "Synthetic mesh augmentation of anterior wall prolapse repair improves anatomic outcomes and bulge symptoms compared with native tissue repair. Biologic grafts do not improve prolapse repair outcomes in any compartment. Mesh erosion occurred in up to 36% of patients, but reoperation rates were low."

Women who suffer from POP frequently complain of dyspareunia, which has many different causes and is commonly seen in women who've never had a mesh surgery. Pelvic floor surgery may cause dyspareunia or pain whether the repair uses native tissue or is graft augmented (Francis, 1961). This fact has been a matter of common surgical knowledge for decades. A study by Lowman in 2008 compared the effects of native tissue repairs (USLS, SSLS, ASC, Ant/Post Colporrhaphy) with Prolift mesh repairs and found a lower rate of postoperative dyspareunia with Prolift (Lowman, 2008). On balance, the totality of medical literature does not support plaintiffs' experts claim that Prolift causes greater rates of dyspareunia or sexual dysfunction than native tissue repairs. Prior to the launch of Prolift, "dyspareunia [was] a major post-operative complication" of POP repair (Kahn 1997) and by 2007 remained a

"frequent and difficult postoperative problem" (ACOG 2007). Before Prolift, "long term debilitating pain" and "severe" dyspareunia were noted in POP-repair patients who were unable to perform their jobs and saw their daily activities limited due to these complications (Barksdale 1997). Another pre-Prolift study noted that there was a "substantial prevalence of dyspareunia after posterior colporrhaphy of 21% to 27%" (Weber 2000). Even as early as 1961 "apareunia and dyspareunia [were] well-accepted complications of operations which involve incision and suture of the vagina..." (Francis 1961). A 1995 study noted that "Major complications have been encountered while performing transvaginal sacrospinous colpopexies. These include pudendal artery laceration, which may lead to massive hemorrhage and injury to the pudendal or sciatic nerve, leading to chronic pain syndromes" (Verdeja 1995). In short, pain, dyspareunia and recurrent prolapse have long been a vexing problem for surgeons when it comes to POP repair (Weber 2004). Prolift presented a less invasive and more reliable and effective approach to treating POP while not increasing the risk of post-operative complications like pelvic pain or dyspareunia. In fact, a recent meta-analysis of RCTs comparing trans-vaginal mesh to native tissue repairs concluded the following: "Sexual function and de novo and postoperative dyspareunia were similar between the patients who underwent TVM repair and those who underwent native tissue repair" (Liao 2019).

Plaintiffs' experts have also claimed that the Prolift mesh causes excessive contraction or shrinkage, which then leads to pain and anatomical distortion. This claim fails to account for the fact that it's a matter of common knowledge to surgeons that tissue contraction (which may cause some degree of mesh contraction in turn) is an expected and basic elemental component of all pelvic floor surgery. In the case of Prolift, the rate of complications stemming from contraction was very low—.4% in De Landsheere's 2012 study.

Taken as a whole, the large volume of data indicate that Prolift POP repairs using Gynemesh PS was safe and effective with cure rates, both subjective and objective,

better than native tissue repairs. Between the two approaches, there is no difference in the incidence of pelvic pain, vaginal pain or dyspareunia, and no difference with respect to sexual function. While plaintiffs' experts cite various mesh exposure rates associated with Prolift, they fail to take into account the fact that native tissue and suspension based repairs are also associated with suture erosions and exposures, often at rates higher than that of mesh erosion seen following Prolift (Toglia 2008; Yazdany 2010; Abed 2011; Barber OPTIMAL trial).

Mesh Used with Prolift

Graft materials to augment POP surgery have been used for over 30 years. Multiple studies have reported that the biologic graft products have proven to be unsatisfactory (Fitzgerald, 1999, Huang, 2001). Furthermore the biologic grafts have not proven superior to native tissue (Paraiso, 2006, Maher, 2016).

Synthetic mesh products have been used in surgery for many years. Within the field of pelvic floor surgery, this use was prompted by a desire to find a substitute for autologous fascia in the pubovaginal sling (PVS) procedure since the harvesting of fascia from a patient was associated with increased morbidity in the form of wound complications. Dr. TeLinde reported using a Mersilene sling in 1962. In 1966, Dr. Ridley reported on complications with Mersilene including erosion into the bladder.

In 1996, Dr. Norris described their experience with multiple mesh materials including Marlex, Silastic, Mersilene, Teflon, and GoreTex and the complications associated with use of these materials. Suffice it to say that synthetic mesh materials and the potential complications associated with their use were well known within the field of gynecology and pelvic floor surgery long before Prolift was introduced.

The quest for finding a synthetic graft material with low risk of complications continued. In 1994, Amid categorized synthetic materials used in hernia repair based on a number of attributes. He created a list with four subtypes. Type 1 is characterized by being made from knitted monofilament strands with pore size

exceeding 75 microns. He also described why polypropylene was superior to other synthetic products stating that it is completely inert, resists infection and sinus tract formation, has rapid fibrinous fixation, becomes completely incorporated into the host tissue, and in case of infection does not have to be removed. The Gynemesh PS used with Prolift and the later Ultrapro mesh used with Prolift+M is Amid Type 1, a large pore lightweight mesh (AUGS/SUFU 2014).

In 2003, Dietz compared the properties of eight different synthetic implant materials and found that the Gynemesh PS mesh used in the TVT had a very low erosion rate.

In the initial TVT trials using polypropylene mesh, Dr. Ulmsten found no unacceptable rates of infection, rejection or impaired healing (Ulmsten 1998). Another study based on biopsies 2 years following implantation found no evidence of host tissue reaction (Falconer 2001).

In 2015, the Cochrane review on MUS stated the type 1 polypropylene mesh was the most biocompatible synthetic material for use in the pelvic floor. In addition, it is the favored graft material for hernia repairs and has significantly enhanced success of hernia surgery (Cobb 2005).

In addition, longitudinal studies were being done on the TVT sling that reported lasting efficacy and no increase in adverse events 17 years following implantation (Nilsson, 2013; Braga 2018; Bakus 2018).

Claims by Plaintiffs' experts that a safer alternative design to Prolift or Prolift +M exists is without merit. The TVM group considered Vypro and concluded it was not a viable option (Jacquetin 2004). While it was thought in the mid 2000s that Ultrapro, which contains an absorbable Monocryl component and is lighter weight than Gynemesh PS, would produce less inflammation and scarring (and thus lead to fewer complications), the medical literature has demonstrated equivalency between

Prolift and Prolift +M, which incorporated Ultrapro as its mesh in 2009. Milani's 2012 three year follow-up found a 15% exposure rate and 9% rate of de novo dyspareunia with Prolift +M. When compared to Prolift, no discernable difference in exposure or re-operation rates were found with Prolift +M (Quemener 2014). In short, while Prolift +M has demonstrated it safety and efficacy (Khandwala 2013 and 2014), its use of Ultrapro mesh did not demonstrate an ability to eliminate or even significantly reduce the risk of post-operative complications like mesh exposure, pain, dyspareunia or urinary problems.

Mesh related complications

Wound complications are common with vaginal surgery. A NIH sponsored randomized controlled trial compared the USLS and SSLS native tissue suspensions reported the presence of persistent granulation tissue (USLS 19%, SSLS 14%) and, as noted above, suture erosions (USLS 15%, SSLS 17%) were common problems (Barber 2014).

Mesh exposure is the only complication unique to Prolift compared with other vaginal native tissue repairs. Although infection has been claimed to be the underlying cause for exposure, data do not support this hypothesis. A study of 524 patients followed for 38 months after Prolift implantation reported a 0.2% reoperation rate due to infection. Furthermore, reoperation for mesh exposure was only 2.5% (Landsheere 2012).

Another study reporting on 75 patients following Prolift repairs for 54 months found an 85% cure rate and a mesh exposure rate of 5.3%. Two of these were successfully treated conservatively while only two required repeat surgery. There were no infections.

The incidence of mesh exposure with Prolift or Prolift + M in most studies is similar to the exposure rate with the sacrocolpopexy operation. In one of the original TVM studies, the exposure rate in 648 cases was 11% when concomitant hysterectomy

was performed, 4.7% without hysterectomy (Caquant, 2008). A large well-respected study on abdominal sacrocolpopexy reported a mesh exposure rate of 10.5% (Nygaard).

Mesh exposure may also be caused by hematoma formation following surgery. This collection of blood will either liquefy and resorb or create pressure and drain through the incision. If this occurs, the wound separation exposes the underlying mesh and the wound edges will not seal closed because of adherence to the mesh. This can be treated with a simple excision of the exposed mesh, often within an office setting. With larger exposures, anesthesia may be required, but the revision may preserve the bulk of the mesh and simply remove the area exposed, reapproximating the edges of vaginal tissue over it.

FDA

In 2008, the FDA published a Public Health Notification: Serious *Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence.* The purpose was to notify the public of the potential for adverse events when mesh was used in pelvic surgery and to counsel patients on these potential dangers.

In 2011, the FDA published an updated notice specifically addressing POP products. This report stated, "Following the *PHN*, the FDA continued to monitor the outcomes of urogynecologic use of surgical mesh. A search of the FDA's Manufacturer and User Device Experience (MAUDE) database from the last 3 years (January 1, 2008 - December 31, 2010), identified 2,874 Medical Device Reports (MDRs) for urogynecologic surgical meshes, including reports of injury, death, and malfunctions. Among the 2,874 reports, 1,503 were associated with pelvic organ prolapse (POP) repairs, and 1,371 were associated with stress urinary incontinence (SUI) repairs.

In the same notification, the FDA stated that between 2008 and 2010, approximately

75,000 transvaginal mesh repairs were performed in the United States each year. Placing these available figures in context, this would indicate that there were 1,503 complications out of 225,000 cases or a rate of 0.7%. Furthermore the majority of these complications were related to mesh exposure, a complication that is, by in large, easy to treat. It was this report from the FDA that opened the door for a deluge of litigation against the manufacturers of the POP devices.

In response to the FDA PHN, the Pelvic Surgeons Network issued an article entitled "Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: Update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse." In its summary this article stated, "The fundamental flaw in the FDA's analysis is that it is based on the question of proof of superiority of mesh in all patients. No one is suggesting that mesh is recommended for all patients. However, there may be instances when a surgeon suspects that a native tissue repair will have a high risk of failure and that the potential benefits of a mesh repair outweigh the risks. The purpose of this response is to demonstrate that TVM is an important tool in our surgical armamentarium that may be the best option in some cases. From our vantage point, it appears that the FDA has presented a biased view of TVM among all POP repair procedures because of the current reporting mechanisms in place." I am personally in agreement with this statement.

Unforeseen adverse events such as granulation tissue, wound disruptions, erosions of suture or graft material can complicate all POP surgeries. These have all been recognized for many years and are part of the basic training of every medical student and surgeon. Furthermore, all adverse clinical outcomes following these procedures are regular subjects of discussion within our professional journals and meetings.

It is probably appropriate to mention, at this point, that because Prolift is both a procedure and a product, the number of these procedures corresponds exactly to

the number of products sold. In contrast, there is no way to accurately know how many native tissue POP procedures were done annually or over any interval of time. Consequently, there is no way to accurately know what the rate of complications is with the native tissue repairs. Estimates are based on studies that are often biased by the technical proficiency of the author/surgeon as well as a host of other potential biases.

My experience treating POP

I became an early adopter of the transvaginal tape (TVT) in 1998. This product produced by Ethicon (Gynecare) uses the same Prolene material used in Gynemesh PS used in Prolift products that would be introduced 7 years later. Prior to the introduction of TVT in the United States, Dr. Ulmsten and his European colleagues who founded TVT performed extensive studies and accumulated a voluminous experience. Although the TVT was not introduced into the United States until 1998, they had done many cases with the original prototype referred to as intravaginal slingplasty, and had begun publishing their results as early as 1996.

Initially, as soon as I became satisfied that the chances of causing harm were negligible, I could not refrain from offering this minimally invasive procedure. The claims of efficacy were impressive and were substantiated by a large volume of further studies. Furthermore, if the TVT failed, one of the more invasive urethropexies could still be performed with the patient having previously undergone only minor surgery. This line of reasoning compelled me to offer the TVT to my patients. Quickly, my favorable impression was reinforced by the reports I received from an almost universally happy group of patients. Within a very short period of time, other reports and studies corroborated my experience.

Based on this favorable experience with TVT and the paucity of adverse events, I adopted Prolift into my armamentarium for treating POP sometime in either late 2005 or early 2006. As with TVT, my experience was quickly reinforced by the good results I was seeing and the favorable reports from my patients.

In 1998, I became a preceptor for Gynecare, initially to train other physicians on the use of the MUS and later on the use of Prolift. Between 2006 and 2012, I taught hundreds of physicians how to perform the Prolift procedure. After the introduction of Prolift + M, I also used and taught that. In my instruction, I provided a cadaver lab experience through the University of South Alabama's department of anatomy. In this setting preceptees could actually perform the procedure on a cadaveric specimen and see the anatomical relationships between the trocars used to insert the mesh and the surrounding structures.

Following the lab, they accompanied me into the operating suite to watch live surgical procedures. This experience was further supported by reviewing the instructions for use (IFU) as well as a discussion of potential complications and how to handle them should any arise. No limitations were placed on these discussions and all involved were encouraged to discuss any and all potential complications.

During these years that I served as a preceptor, I also attended meetings in other cities designed to educate other general ObGyn physicians about the Prolift products. In addition, I attended an annual summit meeting for all of the preceptors around the country hosted by Gynecare. These were always extremely helpful because it provided a unique opportunity to focus with all of the thought leaders in the field on one subject. I was always impressed with the way Gynecare conducted these events. They provided the venue and opened the floor for the physicians to discuss anything and everything regarding the treatment of POP and their clinical outcomes. There was never a preconceived agenda that might discourage open conversation. In fact, the Gynecare representatives were always looking for any kind of feedback – positive or negative – that could help them improve their products.

What Other Adverse Claims Have Been Made About The Use Of Polypropylene Mesh?

There have been many allegations as to the harmful effects of the polypropylene used with Prolift and TVT products.

"Roping" and "curling" of the mesh is said to occur frequently and, as a result, cause complications. The arms of the Prolift products (four in the anterior Prolift, two in the posterior Prolift, and six in the total Prolift) were covered with a plastic sheath and not removed until the mesh had been positioned properly. By design, this served an important purpose; preserving the architecture of the mesh before any tension was applied. The mesh was implanted with the sheaths intact. Once the proper tensioning was established, the sheaths were removed and the surgeon could clearly see that the mesh had not stretched and, therefore, not roped or curled.

"Cytotoxicity" is another claim. A number of plaintiff expert witnesses have claimed that the polypropylene has a cytotoxic effect. By destroying the cell layer overlying the mesh, it is hypothesized that mesh exposure results. The weight of the scientific evidence contradicts this claim. The biocompatibility of Prolene has been well established since the FDA first cleared Prolene sutures for use a half century ago. Since then, Prolene has been used in practically every surgery in billions of patients. Moreover, professional societies around the planet have affirmed the biocompatibility of Prolene mesh for use in vaginal surgeries (see the 2018 AUGS/SUFU position statement which was also endorsed by ACOG).

If cytotoxicity is an inherent property of polypropylene, observations of resulting adverse events should be far more commonplace and should have become evident years before the TVT was introduced. Polypropylene has been used in the form of suture material for decades for surgery throughout the entire human body.

Plaintiff's claim that Prolene mesh degrades is also without merit. I'm aware of no medical literature that supports the conclusion that Prolene mesh degrades in any clinically meaningful way. Plaintiffs claim that Clave 2010 supports Prolene degradation is unsupported and does not demonstrate degradation. In fact, studies demonstrate just the opposite (Thames 2017) and that plaintiffs' claims that the Prolene fiber undergoes a "barking" barking process are without merit. AUGS/SUFU (2014 FAQ) has addressed the question of degradation and concluded the following:

"Does the MUS mesh made of polypropylene degrade over time?
Polypropylene is a stable and well-accepted biomaterial with a history of over five decades of use in mesh implants. In recent years, concerns regarding implanted polypropylene degradation have been raised as a result of very high-AUGS-SUFU FAQs by Providers on Mid-urethral Slings for SUI -2- magnification images that show portions of some explanted synthetic meshes with "cracked" surfaces. These surface changes were further hypothesized to lead to adverse clinical outcomes, though this is not supported by the extensive peer-reviewed literature related to polypropylene mesh repairs. Prospective studies have followed patients with implanted mid-urethral slings for 17 years and show excellent durability and safety of the procedure."

I agree with this statement.

"Chronic inflammatory reaction" is another charge made about mesh. Every foreign body creates some inflammatory response in the host. That is a normal, expected finding and one that is not harmful. Prolene mesh, like any biocompatible foreign body may illicit an acute or transient foreign body reaction upon initial implantation. To the extent the foreign body reaction continues in the long-term, it is of no clinical significance and does not result in complications like pain or mesh contraction. Additionally, studies have shown ideal tissue reaction with TVT, which contains a heavier weight and smaller pore mesh than the Gynemesh PS used in Prolift (Falconer C. Int Urogyn J 2001). Infection is a risk of any surgery. The clinical literature regarding the infection rate of TVT mesh is very low. In fact, wound complications with TVT are less than that with non mesh repairs like Burch and the pubovaginal sling. (Schimpf, 2014). This is consistent with my experience. Of note,

De Landsheere found in his three year study that the rate of mesh related infection requiring surgery occurred in only one out of 524 patients (De Landsheere 2012).

"Carcinogenisis" or the risk that that polypropylene causes cancer is another claim. No evidence is available that Prolene, Gynemesh PS or Ultrapro mesh are causes cancer. Reliable data do not show a risk of sarcoma or cancer. (Moalli P., Int Urogyn J 2014; King 2014; Linder 2016).

Instructions for Use

The instructions for use provided with Prolift and Prolift +M were adequate and appropriately warned surgeons of any risks that were unique to those products. Plaintiff experts have alleged that all Prolift IFUs are deficient. However, these claims are without merit. Risks pertaining to pelvic pain, dyspareunia, vaginal scarring, infection, re-operation and voiding dysfunction are commonly known basic elemental risks of vaginal surgery in general and have been known as such for decades. Pelvic floor surgeons understand and are familiar with these risks from their education, training, clinical experience and ongoing review of the medical literature. Importantly, these risks have been well reported in the medical literature and textbooks before Prolift was first sold in 2005 (Moore 1955; Francis 1961; Williams 1962; Morgan 1970; Amias 1975; Stanton 1985; Galloway 1987; Haase 1988; Kahn 1997; Kholi 1998). In fact, mesh erosion/exposure is the only risk unique to mesh products and this risk is not only warned about in the Prolift labeling, but has been well known as a basic elemental risk of mesh surgery for decades. In addition to the publicly available medical literature, Ethicon provided doctors like myself professional educational opportunities in which the risks and potential complication associated with MUS surgery was discussed. Professional education slide decks and the Prolift Surgeons monograph (2007) also provided additional risk information to doctors.

Summary

Pelvic organ prolapse is a huge problem in our country and it imposes a tremendous physical, psychological, and economic burden on the millions of women who suffer from it.

Prior to the introduction of Prolift and other mesh augmented POP repair products, there existed a general frustration among pelvic reconstructive surgeons regarding the high failure rates of vaginal procedures within this domain. At the time ASC was the gold standard operation, but this was before laparoscopic techniques had been introduced and perfected. As a result, even though ASC was very effective, it was associated with significant morbidity, long operating time and long recovery time.

Many surgeons therefore, joined the search for vaginal reconstructive procedures that could provide results comparable with ASC. Initially, this took the form of using various biological and synthetic products to augment the native tissue repairs. Eventually, macroporous polypropylene mesh rose to the top as the product that provided excellent support and superior durability while displaying host tolerance with no rejection or infection, excellent tissue incorporation, and low erosion rates.

The remaining challenge was to find a technique that would be easily teachable and reproducible. The first product to answer the challenge was introduced by American Medical Systems with their Apogee and Perigee devices. The Ethicon Prolift products followed within a few months. The pelvic floor surgery community quickly embraced these because considerable research and well-designed European studies preceded their debut into the United States. Rigorous studies continued in this country and further documented excellent outcomes and low complication rates.

At the time that I incorporated Prolift into my practice armamentarium, I had already accumulated six years of experience using Prolene mesh with Ethicon's midurethral sling products. My outcomes had been extremely favorable and there were few mesh related complications that could not be explained by user error.

These included slings that were introduced too superficially and those that had been tensioned too tightly.

With this background, the challenge I faced had nothing to do with potential complications related to the use of mesh, but rather, the technique for implantation. After attending both cadaver laboratory events sponsored by Ethicon and live surgery performed by someone proficient in placing Prolift, I became convinced that Prolift products represented another significant advance in the field of pelvic reconstructive surgery similar to the revolutionary midurethral slings in the treatment of stress urinary incontinence.

Major abdominal surgery was substituted with much less invasive vaginal surgery and prolonged postoperative pain with short-term minimal pain. Even better, success, both subjective and objective, was as good as, and most of the times better than, with the former operations whether they used native tissue or, in the case of ASC, synthetic mesh.

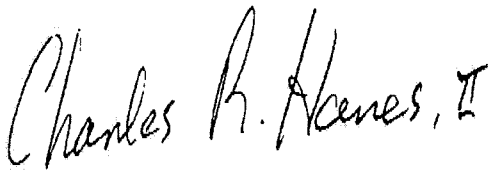
My experience was very good with the Prolift products. I did encounter postoperative complications but no more than what I would reasonably expect from other POP repairs not utilizing mesh.

Not implanting the mesh too superficially in the vaginal tissue is one of the most important components for success. Failure to do so results in mesh exposure and dyspareunia. The other vitally important component is making certain that the mesh is implanted under very light tension. Over-tensioning results in pain and dyspareunia. Proper adherence to the implantation instructions in the Prolift IFU, Technical Guide and Surgeon's Monograph avoids these issues.

I firmly believe that there remains a strong need for the surgical option of transvaginal mesh-augmented pelvic floor repair. I also believe that the benefit of transvaginal mesh in properly selected patients outweighs the risk of mesh related

complications and that, when complications do arise, they are, for the most part, easily resolvable.

I reserve the right to supplement or modify my expert opinion based on the discovery, disclosure and timely provision of new findings and the depositions of Plaintiffs' experts. All of the above opinions are held to a reasonable degree of scientific and medical certainty.



Charles R. Hanes, II, MD
June 23, 2019

Charles Hanes

General Materials List
in Addition to Materials Referenced in Report

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Zullo M A, F Plotti, M Calcagno, E Marullo, I Palaia, F Bellati, S Basile, L Muzii, R Angioli and PB Panici. One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence: a prospective randomised trial. Eur Urol 2007; 51(5): 1376-82; discussion 1383-4.

Charles Hanes Materials List

Medical Literature

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Zyczynski HM, et al. (Prosima Study investigators) One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. Am J Obstet Gynecol 2010; 203: 587.e1-8.

Charles Hanes Materials List

Production Materials

2001 TVT Surgeon's Monograph
000001_4275674_d_Use of Gynemesh PS in Prolapse Surgery Power Point
2003 Gynemesh PS Early Clinical Experience White Paper
2003 Gynemesh PS white paper. Gynemesh PS Early Clinical Experience.
2004 Gynemesh PS Study Poster - AUGS 2004 San Diego. Lucente V, Hale D, Miller D, Madigan J. A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse.
2007 Prolift Prof Ed Slides
Clinical Evaluation Report - Gynemesh PS by Piet Hinoul - April 26, 2013
ETH.MESH.00012009-089 - TVM Prospective Data (French Trial) - Exhibit 522
ETH.MESH.00013529-534 - Prolift+M IFU
ETH.MESH.00018382 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the Treatment of Pelvic Organ Prolapse
ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP - Pelvic Floor Surgery and Anatomic Dissection Lab
ETH.MESH.00167104 - 2006 TVT Laser Cut Clinical Expert Report
ETH.MESH.00295355 (TVTE-338-10-7.12) - 2010 TVT-Exact Prof Ed
ETH.MESH.00308094 (2629_2006-07-12) - 2006 TVT-Secur
ETH.MESH.00354732 (TVTA-088-11-2.13) - 2011 TVT-Abbrevo
ETH.MESH.00369995 (2008-570) - 2008 TVT Family of Products Prof Ed
ETH.MESH.00369999 (2008-135) - 2008 TVT-Secur
ETH.MESH.00370421 (TVTO_0113-09-8.11) - TVT-O FDA Public Health Notice
ETH.MESH.00373310 (2003-712) - 2003 TVT Prof Ed
ETH.MESH.00393045-46 (2008-582) TVT-O Procedural Steps
ETH.MESH.00394849 - Gynemesh PS Panel Powerpoint - Drs. Robinson, Miller, Winkler, England
ETH.MESH.00395374-380 - 2001 June 22; Scientific Advisory Chicago Meeting re POP mesh includes Prolene Soft
ETH.MESH.00397674 (2002-275) - 2002 Minimizing & Managing TVT Complications Prof Ed
ETH.MESH.00520649-722 - 2006 US TVM 12 Month Clinical Report
ETH.MESH.00523617 (2007-4144) - 2007 TVT-Secur Critical Steps
ETH.MESH.00523942 (2005-1638) Waltregny TVT-O Summit
ETH.MESH.00637343 - 2004 ETHICON Product Development Process - Gynemesh PS
ETH.MESH.00747864-874 - Gynemesh PS DDSA Rev.
ETH.MESH.00747864-874 - Gynemesh PS DDSA Rev. 2
ETH.MESH.00993273 (2091_2006-02-01) - 2006 TVT-O Summit Presentation by Raders and Lucente
ETH.MESH.01128679-98 (TVTS007) - 2007 TVT-Secur Procedural Steps
ETH.MESH.01222075 - 2006 Kammerer Memo
ETH.MESH.01261962 (2005-1819) - TVT-O Summit by Raders, Rogers, Lucente
ETH.MESH.02219584 - 2010 Scion PA Unmet Needs Exploratory Research
ETH.MESH.02330776 (TVTO-384-10-8.12) - TVT-O
ETH.MESH.02341398-410 - Prosima IFU
ETH.MESH.02341454-459 - Prolift 2007-2009 IFU
ETH.MESH.02341522-527 - Prolift 2005-2007 IFU
ETH.MESH.02341658-664 - Prolift 2010-2012 IFU - Text Searchable
ETH.MESH.02341734-740 - Prolift 2009-2010 IFU
ETH.MESH.02342097 Prolene Soft IFU
ETH.MESH.02342101 Prolene Soft IFU
ETH.MESH.02342102 Prolene Mesh IFU

Charles Hanes Materials List

Production Materials

ETH.MESH.02342152-54 Prolene Mesh IFU
ETH.MESH.02342194-196 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342218-220 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342250-252 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342278-279 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02603812-821 - Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh
ETH.MESH.02616825-27 Prolene Soft IFU
ETH.MESH.03458123-38 - TVT Patient Brochure 3.19.08
ETH.MESH.03460813-853 - Prolift Surgeons Resource Monograph 2007
ETH.MESH.0370392 (3914_2007-08-22) - 2007 TVT-Secur
ETH.MESH.03715787-793 - Gynemesh PS CER (2002) - Weisberg
ETH.MESH.03751819 (2009-473) - 2009 The Science of What's Left Behind
ETH.MESH.03905968-975 - Prolift 2005 Brochure
ETH.MESH.03905976-991 - Prolift 2006 Brochure
ETH.MESH.03906001-020 - Prosima and Prolift+M
ETH.MESH.03906037-052 - Prolift 2008 Brochure
ETH.MESH.04046302 (TVT and TVT-O)(2005-1117)
ETH.MESH.04079609 (TVTA-401-10-8.12) - 2010 TVT-Abbrevo
ETH.MESH.04202101 (2008-448)
ETH.MESH.05222686-88 - TVT IFU (4th version) 4.7.06-10.7.08
ETH.MESH.05320909 (2008-135)(38 slides summit) - 2008 TVT-Secur
ETH.MESH.05795421 (2001-227) - 2001 TVT Prof Ed
ETH.MESH.05795537 (1998-218) - 1998 TVT Prof Ed
ETH.MESH.07201006 - Prolift Prof Ed 2007 Slide Deck
ETH.MESH.07246690-19 - Study Report - A systematic review of patient-years of experience in prospective randomized controlled trials (RCTs) in incontinence.
ETH.MESH.08003279-94 - TVT Patient Brochure 12.10.08
ETH.MESH.08117473 - 2012 TVT-Exact Updated Prof Ed Slide Deck w Production Cover
ETH.MESH.08156958 (2002-310) - 2002 TVT Advanced Users Forum Presentation
ETH.MESH.08307644-45 - 4.05.2013 - Email from P. Hinoul to G. Callen re: RCT data (with attachments).
ETH.MESH.09100506 - Prolift Prof Ed 2005 Slide Deck
ETH.MESH.09744840-45 - TVT Patient Brochure 2.14.13
ETH.MESH.10027307-28 - Surgeon's Resource Monograph
ETH.MESH.10686760-771 - Gynemesh PS aFMEA 2013
ETH.MESH.10686833-852 - Risk Management Report (RMR) for Gynemesh PS 2013
ETH.MESH.11543641 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
ETH.MESH.11543719 - Robinson Gynemesh PS Presentation Awareness Module 4.7.04
ETH.MESH.22625140-45 - MDD CAPA # CAPA-003474
ETH.MESH.22631022-29 - Response to Section 39 Request, D-1, 1-1002
ETH-02288-289 - Gangam N. Retroperitoneal hemorrhage after a vaginal mesh prolapse procedure. Obstet Gynecol 2007; 110: 463-4
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Production Materials

ETH-02421-422 - Nogueira B. Vaginal Erosions as Delayed complications of sling procedures. [ABS 229] Int Urogynecol J 2006; 17(Suppl 2): S187
ETH-02794-799 - Collinet P, et al. Transvaginal mesh technique for pelvic organ prolapse repair: mesh exposure management and risk factors. Int Urogynecol J 2005; Epub Ahead of Print
ETH-02813-817 - de Tayrac R, et al. Long-term anatomical and functional assessment of trans-vaginal cystocele repair using a tension-free polypropylene mesh. Int Urogynecol J 2006; 17: 483-488
ETH-02955-961 - Deffieux X, et al. Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study. Int Urogynecol J Epub Ahead of print 2005
Gynecare Gynemesh PS IFU (English Only) LAB-0012266 Rev: 3, released 02.03.15.
Gynecare TVT IFU changes redlined, D-6, 1-20
Gynemesh PS 510k Approval File [FDA]
Gynemesh PS white paper - Early Clinical Experience
K013718 GYNEMESH PS (Ethicon) Corrected SE Letter (07-Nov-2012)
May 2010 CER for Gynemesh PS signed by David Robinson
PS120046 A2 - 7.9.12 FDA Response to Ethicon re Gynemesh PS
TVT IFU (7th version) 2015 - Present - from Ethicon website.

Charles Hanes Materials List

Company Witness Depositions

Hinoul, Piet - 01.15.2014 Deposition Testimony
Weisberg, Martin - 11.13.2015 Deposition Testimony

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Other Materials

2008 FDA Public Health Notification: Serious complications associated with transvaginal placment of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence.
2011 IUGA Patient Brochure - Vaginal Repair with Mesh Patient Brochure
2012 ABOG and ABU Guide to Learning in Female Pelvic Medicine and Recontructive Surgery.
2012 ABOG Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery
2012 AUA Guidelines - Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update - Appendices A11 and A16
2013 AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence.
2013 AUGS Guidelines for Privileging and Credentialing Physicians for Sacrocolpopexy for Pelvic Organ Prolapse
2013 FDA Statement regarding Considerations about Surgical Mesh for SUI
2014 IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence
2015 ACOG Practice Bulletin #155 Summary - Urinary Incontinence in Women, 1120-1122
2016 AUGS, SUFU, ACOG, SGS, AAGL, NAFC,WHF, Position Statement - Mesh Midurethral Slings for Stress Urinary Incontinence
2016 August - ICS IUGA ACOG AUGS AUA SUFU - Groups reaffirm position on use of vaginal mesh for surgical treatment of stress urinary incontinence
2016 IUGA Patient Brochure on Midurethral Sling Procedures for Stress Incontinence
2017 ACOG, AUGS - Committee Opinion on Complications in Gynecologic Surgery, 1-6, Management of Mesh and Graft Complications in Gynecologic Surgery.
2017 AUA, SUFU Guideline - Surgical Treatment of Female Stress Urinary Incontinence, 1-33
2018 AUGS, SUFU, AAGL, ACOG, NAFC, SGS, Position Statement - Mesh Midurethrethral Slings for Stress Urinary Incontinence
2018 July - IUGA Global Statement in support of MUS for SUI
2018 RANZCOG Position Statement on SUI and POP
ACGME Program Requirements for Graduate Medical Education in Female Pelvic Medicine and Reconstructive Surgery
ACOG Practice Bulletin Summary Urinary Incontinence in Women. Replaces Practice Bulletin Number 63, June 2005. 2015; 126(5)
American Urogynecologic Society Board of Directors. Position statement on restriction of surgical options for pelvic floor disorders: the American Urogynecologic Society Board of Directors. Female Pelvic Med Reconstr Surg. 2013 Jul-Aug; 19(4): 199-201
AUA. Position Statement on the Use of Vaginal Mesh for the Repair of Pelvic Organ Prolapse. November 2011; reaffirmed October 2016 and October 2018
AUGS Residency Guidelines
AUGS Resident Learning Objectives
AUGS/SUFU Mesh Midurethral slings for stress urinary incontinence. 2014, Updated 2016.
Code of Federal Regulations Title 21, as of 4/1/15. 21CFR801.109
Committee on Practice Bulletins-Gynecology, American Urogynecologic Society. Practice Bulletin No. 185: Pelvic Organ Prolapse. Obstet Gynecol. 2017 Nov; 130(5): e234-e250.

Charles Hanes Materials List

MDL Wave Cases

Expert Reports
Blaivas, Jerry (Prolift General) - 01.17.2017
Blaivas, Jerry (TVT Abbrevo General) - 01.17.2017
Blaivas, Jerry (TVT Exact General) - 01.17.2017
Blaivas, Jerry (TVT-O General) - 01.17.2017
Elliott, Daniel (Prolift General)
Elliott, Daniel (TVT-O General) - 05.22.2017
Guelcher, Scott (General)
Guelcher, Scott (Wave 5 General)
Iakovlev, Vladimir (General) - 01.29.2016
Iakovlev, Vladimir (Wave 10 General) - 02.20.2019
Iakovlev, Vladimir (Wave 10 General) - 02.20.2019
Klinge, Uwe (POP General) - 11.17.2015
Klinge, Uwe (TVT General) - 11.16.2015
Margolis, Michael (TVT General) - 05.21.2017
Mays, Jimmy (General) - 05.22.2017
MDL Wave 9 and 10 Plaintiff General Reports
Ostergard, Donald (General) - 05.19.2017
Pence, Peggy (General TVT) - 10.14.2013
Pence, Peggy (General TVT-O) - 7.17.2014
Pence, Peggy (Notice of Adoption of Prior Reports) - 2.01.2016
Pence, Peggy (Prolift General) - 07.17.2014
Pence, Peggy (Supplemental General TVT & TVT-O) - 3.2.2016
Pence, Peggy (Supplemental General TVT-O) - 4.24.2015
Priddy, Duane (General)
Rosenzweig, Bruce (Prosima General) - 05.22.2017
Rosenzweig, Bruce (TVT Abbrevo General) - 05.22.2017
Rosenzweig, Bruce (TVT Exact General) - 05.22.2017
Rosenzweig, Bruce (TVT General) - 05.22.2017
Rosenzweig, Bruce (TVT General) - 06.09.2014
Rosenzweig, Bruce (TVT General) - 08.24.2015
Rosenzweig, Bruce (TVT General) - 10.14.2013
Rosenzweig, Bruce (TVT Supplemental General) - 01.06.2017
Rosenzweig, Bruce (TVT, TVT-O Notice of Adoption of Prior Reports) - 12.15.2015
Rosenzweig, Bruce (TVT-O General) - 02.21.2014
Rosenzweig, Bruce (TVT-O General) - 04.24.2015
Rosenzweig, Bruce (TVT-O General) - 05.22.2017
Shull, Bob (Prolift/Prolift +M General) - 02.01.2016
Zipper, Ralph (Prolift General) - 01.31.2016
Zipper, Ralph (TVT-S General) - 07.27.2017

CURRICULUM VITAE

Charles R. Hanes II, M.D.

BUSINESS ADDRESS:

Urogynecology of Southern Alabama
3 Mobile Infirmary Circle
Suite 401
Mobile, AL 36607

PROFESSIONAL LICENSURE:

Alabama Medical Licensure Commission 2004
License # 00008180

EDUCATION:

Vanderbilt University
Nashville, Tennessee 1963-1967

Tulane University Medical School
New Orleans, Louisiana 1967-1971

POSTGRADUATE TRAINING:

Vanderbilt University - Nashville, Tennessee
General Surgery 1971-1973
Emory University - Atlanta, Georgia
Residency, Ob-Gyn 1975-1978

POSTGRADUATE COURSES:

Update Pelvic and Vaginal Surgery 1998
American Urogynecology Advanced Pelvic Anatomy 1998
American Urogynecology Society Pelvic Surgery 1998
Advanced Pelvic Surgery 1999
CITI Course - Protection of Human Research Subjects, Principle Investigator Training 2004

CERTIFICATIONS:

American Board of Obstetrics and Gynecology - Voluntary Annual Recertification 1998-Present
Board certification - Female pelvic medicine and reconstructive surgery 2013-Present

PROFESSIONAL EXPERIENCE:

Private Practice, Ob-Gyn, Mobile, AL 1979-2000
Medical Director, The Continence Center Of Mobile Mobile Ob-Gyn, P.C. 2001-2007
President Providence Hosp. Med. Staff 1990-1992
Director, Urogyneclogy of Southern Alabama 2007-present
Clinical Adjunct Assistant Professor, Dept. Ob-Gyn, Univ. of South Alabama 2003-present

PROFESSIONAL EXPERIENCE CONTINUED:

Preceptor for Ethicon Women's Health and Urology
Medical Staff - Providence Hospital, Springhill Medical Center, Mobile Infirmary Medical Center, The University of South Alabama
Private Practice-Birmingham, Alabama 1978-1979

MILITARY SERVICE: General Medical Officer U.S. Army 1973-1975

PROFESSIONAL ORGANIZATIONS:

Fellow, American College of Obstetrics & Gynecology 1981-present
Member of American Urogynecology Society 1997-Present
Mobile County Medical Society 1979-Present
Medical Association of The State of Alabama 1978-Present
Member Society Gynecologic Surgeons 2005-Present

OTHER: The Best Doctors in America 2003-present

VOLUNTEER/COMMUNITY EXPERIENCE:

Volunteer Physician, Victory Health Clinic
Medical Director, Sav-A-Life

PUBLICATIONS:

29th Annual Scientific Meeting Society of Gynecologic Surgeons, 2003
"TVT Pilot Study- A modified Technique to Improve Voiding Dysfunction",
C.R. Hanes II, M.D.

Journal of Pelvic Medicine & Surgery, Volume 11, Number 2, pg. 72, March/April 2005:
"Enhanced Preservation of Vaginal Length and Vault Support: A Byproduct of Anterior Compartment Repair Using a Synthetic Mesh Graft",
C.R. Hanes II, M.D. and M.S. Mulekar PhD,
Providence Hospital & Mobile Ob-Gyn, P.C., Mobile, AL

C.R Hanes, F.H. Long. Vaginal Sacral Colpopexy. Female Pelvic Med Reconstr Surg. 2009; 15(2):66.

Charles R. Hanes II. Natural Orifice Sacral Colpopexy. OBG Manag. November 2016; 28(11).

C.R. Hanes. Vaginal Sacral Colpopexy: A Natural Orifice Approach To A Gold Standard Procedure. Female Pelvic Med Reconstr Surg. 2017; 23(5), 875.

CR Hanes, II. Vaginal Sacral Colpopexy: A Natural Orifice Approach To A Gold Standard Procedure. JMIG. 2018; 25(1), 47-52.

PRESENTATIONS:

03/25/2004 - Grand Rounds - University of South Alabama Medical Center, Department of Ob-Gyn, Mobile, AL - "Paravaginal Defects Associated with Vaginal Vault Prolapse: Do they always need to be repaired?"

04/29/2004 - Mobile Bay Ob-Gyn Society, Mobile, AL - "The Surgical Management of Female Stress Urinary Incontinence"

31st Annual Scientific Meeting Society of Gynecologic Surgeons Meeting, 2005
"Enhanced Preservation of Vaginal Length and Vault Support: A Byproduct of Anterior Compartment Repair Using a Synthetic Mesh Graft"

2014 Joint Meeting of the Alabama and Mississippi Section ACOG, 5/8/14
"Vaginal Sacral Colpopexy"

41st Annual Scientific Meeting Society of Gynecologic Surgeons Meeting, 03/24/2015
Academic Roundtable, "Natural Orifice Sacral Colpopexy

10/15/2015 – American Urogynecologic Society Meeting - Academic Roundtable, "Natural Orifice Sacral Colpopexy

26th University of South Alabama Obstetrics and Gynecology Conference, 4/20/17
"Apical Suspension: The Foundation for Success and Durability in Pelvic Reconstructive Surgery"

POSTER PRESENTATIONS:

35th Annual Scientific Meeting Society of Gynecologic Surgeons, 3/30/2009:
"Vaginal Sacral Colpoopexy",
C.R. Hanes II, M.D., F. H. Long, M.D., M.S. Mulekar, PhD

42nd Annual Scientific Meeting Society of Gynecologic Surgeons Meeting, Palm Springs, CA, April, 2016. Natural Orifice Sacral Colpopexy

44th AAGL Global Congress on Minimally Invasive Gynecology, 11/15/15
Virtual Poster, "Natural Orifice Sacral Colpopexy: A New Approach To A Time-Honored Procedure"

VIDEO PRESENTATIONS:

44th AAGL Global Congress on Minimally Invasive Gynecology, 11/15/15
"Natural Orifice Sacral Colpopexy"

42nd Annual Scientific Meeting Society of Gynecologic Surgeons, April 2016
"Natural Orifice Sacral Colpopexy"
C.R. Hanes II, M.D.

RESEARCH EXPERIENCE:

Principle Investigator:

"TVT- A Modified Technique to Improve Voiding Dysfunction", C.R. Hanes, II

"Anterior and Apical Compartment Repair Using a Single Piece of Graft in the Anterior Vaginal Wall - A Descriptive Study" Gynecare

Open-Label, Quality of Life, Post Marketing Trial, Comparing Detrol vs. Ditropan 5 mg. and Ditropan 10 mg. Pharmacia

A Phase 4 Open-Label "Multicenter Assessment of Transdermal Therapy in Overactive Bladder with Oxybutynin TDS (Oxytrol) MATRIX", Watson Laboratories

"TVT and TVTO: A Comparison of Postoperative Voiding Dysfunction. A Comparative Study to show that the TVTO procedure has a lower incidence of voiding dysfunction than the TVT procedure when performed with identical tensioning techniques." Gynecare

Open-Label Phase 4 "SECURE: SANCTURA Study to Evaluate Control of Urinary Systems Resulting From Overactive Bladder" Odyssey Pharmaceuticals, Inc.